

[부록 - erratum]

전기식 온침기에 대한 안전성 및 성능평가 가이드라인 개발 연구

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A Study on Developing Safety and Performance Assessment Guideline for Electronic Warm-Acupuncture Apparatus

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Objectives: This research aimed to develop a guideline for evaluating safety and performance of electronic warm-acupuncture apparatus. With the development of medical devices like electronic warm-acupuncture apparatus with improved performance, convenience and safety measures compared to traditional warm-acupuncture needling, safety and performance guideline is a necessity.

Methods: By referring to existing standards and guidelines of other electronic devices for Korean medicine with heating function, guideline for safety and performance assessment of electronic warm-acupuncture apparatus was drafted

Results: The guideline, presents explanation for adequate temperature and settings of the apparatus, and safety measurements providing against thermal runaway situations along with guidelines for the manual. Guideline for detailed test method for the performance of the apparatus such as accuracy of temperature increase and the timer, and safety unit was also provided. The test items and suggested test methods for the requirements of biological, electrical and electromagnetic safety were referred to Korean approval documents of ministry of Food and Drug Safety.

Conclusion: We proposed the relevant items to verify performance and safety of warm-acupuncture apparatus to assure patient safety and improve the quality of currently developing devices for application in clinical field.

Key Words : Warm-Needle Acupuncture, Guideline, Medical Device Safety, Medical Device Design

In the article cited above, 'Acknowledgments' was missed. The added 'Acknowledgments' is as following.

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